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Application No.	S2002/0988
Date of Filing	20 December 2002
Applicant	HENRY WILLIAM LUPTON, an Irish citizen of Minehill House, Renville West, Oranmore, County Galway, Ireland

Dated this 23 day of December 2003.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S020988

FORM NO. 1 Application No.

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. **Applicant(s)**

Name

HENRY WILLIAM LUPTON

Address

Minehill House, Renville West, Oranmore, County Galway, Ireland.

Description/Nationality

An Irish citizen.

2. **Title of Invention**

"A guide wire for use with a catheter"

3. **Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)**

Previous filing date	Country in or for which filed	Filing No.

4. **Identification of Inventor(s)**

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

HENRY WILLIAM LUPTON

Address

Minehill House, Renville West, Oranmore, County Galway, Ireland; an Irish citizen.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

8. **Agent**

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**

F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed HENRY WILLIAM LUPTON

Date 17 Dec 2002

Application No. S020982

"A guide wire for use with a catheter"

The present invention relates to a guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, and in particular though not limited to a guide wire for use with a catheter.

Guide wires for locating a distal end of a catheter in a remote site in the body of a human or animal subject are known. Such guide wires are commonly used for guiding a catheter along narrow blood vessels to a site in the cardiovascular system of the subject for enabling cardiovascular procedures to be carried out. Typically, the guide wire is introduced through a cannula into a suitable blood vessel in the thigh or arm of the subject and is passed through the blood vessels to the desired site in the cardiovascular system. Once the guide wire has reached the desired site, the catheter is then advanced over the guide wire to the site.

Due to the relatively narrow diameter of the blood vessels through which the guide wire has to pass, and in particular, due to the tortuous nature of the blood vessels of the cardiovascular system, and the number of branching blood vessels, it is essential that the guide wire be of a construction which facilitates bending of the guide wire so that the guide wire can be bent around corners, and can be directed into a desired one of branching blood vessels. Various attempts have been made to provide such guide wires, for example, such a guide wire is described in U.S. Patent Specification No. 4,545,390 of Leary and U.S. Patent Specification No. 4,080,706 of Hellman, et al. While the guide wires described in these two prior art specifications are flexible

and suitable for bending around corners of the blood vessels of the cardiovascular system, they suffer from a disadvantage in that it is difficult to initially direct the guide wire around the corner, and in particular, it is difficult to direct the guide wire from one blood vessel into a branching blood vessel. In order to overcome this problem, the distal portion of known guide wires are shaped for facilitating bending of the distal portion to form a curved distal portion, which can then be directed towards a branching blood vessel into which the guide wire is to be directed, and also for facilitating aligning the guide wire with a corner or bend in the vascular system. However, in general, shaping the distal portion of such guide wires in order to facilitate bending the guide wire into a curved portion leads to a reduction in the torsional rigidity of the distal portion. This is undesirable, since drag exerted on the distal portion by the vascular system can lead to twisting of the distal portion when the proximal portion of the guide wire is being rotated about a central axis of the guide wire for aligning the curved distal portion with a bend or corner in the vascular system or with a branching blood vessel into which the guide wire is to be directed. This is undesirable, and accordingly, there is a need for a guide wire for use with a catheter which overcomes this problem.

There is therefore a need for a guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, which is also suitable for use with a catheter, and which overcomes this problem.

The present invention is directed towards providing such a guide wire, and the invention also provides a combination of a guide wire and a catheter.

According to the invention there is provided an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject defining a longitudinally extending axis, the guide wire extending axially between a proximal portion and a distal portion, the distal portion terminating in a distal end for accessing the remote site, the distal portion being adapted to be shaped to facilitate the forming of a desired curved configuration for facilitating guiding of the guide wire around bends, and having a means for minimising axial twisting of the distal portion.

In one embodiment of the invention the means for minimising axial twisting of the distal portion comprises a reinforcing means for reinforcing the distal portion.

In another embodiment of the invention the reinforcing means extends axially along a part of the distal portion. Advantageously, the reinforcing means extends in a generally axial direction along the distal portion.

In one embodiment of the invention the reinforcing means is provided by a reinforcing ridge, which preferably is an elongated reinforcing ridge.

In one embodiment of the invention the reinforcing ridge tapers in an axial direction from one end of the ridge to the other, and preferably, tapers towards the distal end of the distal portion.

In one embodiment of the invention the reinforcing ridge terminates before the distal

end of the distal portion.

In another embodiment of the invention the distal portion comprises a flattened portion adjacent the distal end, the flattened portion defining a pair of opposite major surfaces, and preferably, a pair of opposite minor surfaces.

In one embodiment of the invention the respective major surfaces are substantially parallel to each other, and in an alternative embodiment of the invention the respective major surfaces taper, and preferably, taper towards the distal end.

In another embodiment of the invention the minor surfaces of the distal portion are parallel to each other, and in an alternative embodiment of the invention taper relative to each other, and may taper towards the distal end or away from the distal end.

In one embodiment of the invention the reinforcing ridge is provided on one of the major surfaces, and in another embodiment of the invention a pair of reinforcing ridges are provided, one reinforcing ridge being provided on each major surface.

In one embodiment of the invention the reinforcing means is formed integrally with the distal portion.

In another embodiment of the invention the distal portion is of metal, and preferably, the reinforcing ridge is formed integrally with the distal portion by forging or by

rolling.

In a still further embodiment of the invention the distal portion is formed integrally with the guide wire from one piece of material.

In another embodiment of the invention an outer sleeve is provided around the distal portion of the guide wire extending from the distal end thereof, and preferably, the sleeve is secured to the distal portion at the distal end thereof.

In one embodiment of the invention the sleeve is of a radiopaque material, or terminates in a radiopaque material, for example, platinum or a platinum alloy, gold, tantalum or other such alloys.

In a further embodiment of the invention the outer sleeve is formed by a tightly coiled spring wound around the distal portion, and preferably, the spring is of stainless steel, and terminates at its distal end in the radiopaque material.

Alternatively, the sleeve is provided by a sleeve of plastics material.

In a further embodiment of the invention the outer sleeve comprises in combination a tightly coiled spring and a sleeve of plastics material.

Further the invention provides in combination the guide wire according to the invention and a catheter.

Additionally, the invention provides the distal portion for connecting to a guide wire.

The invention will be more clearly understood from the following description of some embodiments thereof, which are given by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a side elevational view of a guide wire according to the invention,

Fig. 2 is an enlarged partly cut away side elevational view of the guide wire of Fig. 1,

Fig. 3 is an enlarged partly cut away plan view of the guide wire of Fig. 1,

Fig. 4 is a transverse cross-sectional end elevational view of the guide wire of Fig. 1 on the line IV-IV of Fig. 2,

Fig. 5 is an enlarged side elevational view of the guide wire of Fig. 1 illustrating a portion only of the guide wire of Fig. 1,

Fig. 6 is a side elevational view of the portion of the guide wire of Fig. 5 in a different configuration,

Figs. 7(a) to 8(b) are perspective views of a reference piece and a test piece

representing a portion of the guide wire of Fig. 1 during finite element analysis tests,

Fig. 9 is a view similar to Fig. 3 of a guide wire according to another embodiment of the invention,

Fig. 10 is a transverse cross-sectional end elevational view of the guide wire of Fig. 9 on the line X-X of Fig. 9,

Fig. 11 is a view similar to Fig. 3 of a guide wire according to another embodiment of the invention,

Fig. 12 is a view similar to Fig. 10 of the guide wire of Fig. 11,

Figs. 13 to 15 are top plan views of portions of guide wires according to further embodiments of the invention,

Fig. 16 is a side elevational view of the portions of the guide wires of Figs. 13 to 15, and

Figs. 17(a) to (p) are transverse cross-sectional end elevational views similar to Fig. 4 of guide wires according to further different embodiment of the invention.

Referring to the drawings and initially to Figs. 1 to 4, there is illustrated a guide wire according to the invention, indicated generally by the reference numeral 1, for use with a catheter (not shown) for guiding the catheter to a remote site in the body of a human or animal subject. The guide wire 1 according to this embodiment of the invention is particularly suitable for accessing a remote site in the cardiovascular system of a subject for in turn guiding a catheter to the remote site. Although it will be readily apparent to those skilled in the art that the guide wire 1 is suitable for accessing any remote site in the body, be it in a vasculature system or otherwise. For example, the guide wire 1 is suitable for accessing renal vessels, the neuro-vasculature system, the fallopian tubes, and other such vessels and sites.

The guide wire 1 comprises an elongated wire core 2 of metal, in this embodiment of the invention stainless steel, which defines a longitudinally extending central axis 6, and extends from a proximal portion 3 to a distal portion 4. The distal portion 4 terminates in a distal end 5 which in use forms the leading end of the guide wire 1 as it is being passed through blood vessels in the subject to the site in the cardiovascular system. The wire core 2 along most of its length from the proximal portion 3 is of diameter of 0.008 inches to 0.020 inches, and at 7 commences to taper towards the distal portion 4. The wire core 2 tapers in multiple steps in tapering portions 8 to 10 to the distal portion 4, which are interspersed with non-tapering portions 11 and 13. The distal portion 4 is flattened into a spade type shape for facilitating the formation thereof into a curved configuration, as will be described below, for in turn facilitating guiding of the guide wire 1 through the vessels to and of the cardiovascular system of the subject. A sleeve 12 formed by a pair of tightly

wound helical coiled springs 15 and 19 extend along a portion of the wire core 2 from the distal end 5 and terminate at the initial tapering portion 8. The spring 15 is of radiopaque material, in this case platinum alloy, and is secured to the distal end 5 of the distal portion 4 by brazing or soldering at 14. A ring 21 brazed to the spring 15 and to the guide wire 1 at the non-tapering portion 13 secures the spring 15 to the guide wire 1. The spring 19 is of stainless steel, and is also brazed to the ring 21, and extends to the initial tapering portion 8.

Turning now in particular to the distal portion 4 of the wire core 2, as mentioned above, the distal portion 4 is flattened and defines a pair of opposite major surfaces 16 and 17 and a pair of opposite minor surfaces 18. The major surfaces 16 and 17 taper gradually towards the distal end 5. In this embodiment of the invention the distal portion 4 tapers from a thickness t_1 of approximately 0.06mm to a thickness t_2 of approximately 0.02mm over an axial length of approximately 25mm. The material and the tapering thickness of the distal portion 4 are such as to permit bending of the distal portion 4 into the curved configuration as illustrated in Fig. 6. Curving of the distal portion 4 as illustrated in Fig. 6 facilitates guiding of the guide wire around bends in the blood vessels, and into branching vessels.

A means for minimising axial twisting of the distal portion 4 comprises a reinforcing means, namely, an elongated reinforcing ridge 25 located on the distal portion 4, which extends axially along a part of the major surface 16, and terminates at 26 short of the distal end 5. The reinforcing ridge 25 is formed integrally with the distal portion 4 by forging or rolling. The reinforcing ridge 25 provides sufficient rigidity to

the distal portion 4 for minimising and effectively eliminating axial twisting of the distal portion 4 along its axial length as a result of torque induced in the distal portion 4 as the proximal portion 3 of the guide wire 1 is being rotated about the central axis 6 for facilitating directing the curved part of the tip towards a branching blood vessel into which the guide wire 1 is to be directed, or for axially aligning the curved portion of the distal end 5 with a bend in a blood vessel. In this embodiment of the invention the reinforcing ridge 25 extends for a length 15mm along the distal portion 4 and is of width 0.03mm. The reinforcing ridge 25 tapers from a depth d_1 at 28 to zero depth at 26.

Finite element analysis has been carried out on a test piece which is substantially similar to a section of the distal portion 4 and on a reference piece. The finite element analysis is described with reference to Figs. 7 and 8. The reference piece is illustrated in Figs. 7(a) and 8(a), while the test piece is illustrated in Figs. 7(b) and 8(b).

In order to investigate the torque responses of the test piece and the reference piece, a Finite Element Analysis Method (FEAM) was utilised.

In order to facilitate ease of analysis, the reference piece and the test piece were cut from the same piece of wire and were of equal length, and were rolled to form the appropriate cross-sections, such that the lengths of the two rolled sections remained equal.

The material of both the test piece and the reference piece was 304v stainless steel with a modulus of elasticity of 210Gpa and a Poisson's Ratio of 0.3. For modelling purposes, the material was assumed to be linear elastic in behaviour.

The reference piece and the test piece were constrained in all degrees of freedom in the end plane (z=0) plane. Forces F were applied to the corners of the opposite end in the vertical y-direction as shown in Figs. 8(a) and 8(b). The meshes generated are also shown in Figs. 8(a) and 8(b).

The force F applied to each corner of the reference piece had a magnitude of 0.01 lbf. In order to have the same moment applied to the test piece similar to that of the reference piece, forces were applied to each corner of the model with a magnitude of 0.008772 lbf.

Results

The deformed geometry plots for both the reference and the test pieces when subjected to the loading conditions described above, are shown in Figs. 8(a) and 8(b).

The y-direction reaction forces on the constrained corner nodes of the unloaded end of each of the reference and the test pieces were investigated. The maximum values of these reaction forces in both the positive and negative y-directions are shown in Table 1 below.

Force	Uniform cross-section reference piece	Uniform cross-section test piece	Increase in torque response of uniform cross-section test piece
Max. positive y-direction reaction force	0.94861E-02	0.10974E-01	15.7%
Max. negative y-direction reaction force	-0.94726E-02	-0.11363E-01	20.0%

Table 1: Maximum values of the y-direction reaction forces at the constrained nodes.

Conclusions

It can be seen that the reaction forces, and hence the torque response of the test piece is increased by approximately 15% to 20% over the reference piece.

This result indicates that the guide wire 1 with the distal portion 4 and the reinforcing ridge 25 would have a torque response significantly increased over and above a guide wire with a distal portion similar to the distal portion 4 but without the reinforcing ridge 25.

Accordingly, the provision of the reinforcing ridge 25 on the distal portion 4 significantly reduces twisting of the distal portion 4 about the central axis 6 as a result of torque induced in the guide wire 1, which would otherwise arise in the distal portion 4 without the reinforcing ridge 25.

Referring now to Figs. 9 and 10, there is illustrated a guide wire according to another embodiment of the invention, indicated generally by the reference numeral 30. The guide wire 30 is substantially similar to the guide wire 1 and similar components are identified by the same reference numerals. The only difference between the guide

wire 30 and the guide wire 1 is that the sleeve 12 in this embodiment of the invention as well as comprising the springs 15 and 19 and the ring 21 includes an additional sleeve 32 of plastics material extending from a ring 33 to the initial tapering portion 8. The ring 33 is brazed to the spring 19 and to the wire core 2 at 34. Otherwise the guide wire 30 is similar to the guide wire 1.

Referring now to Figs. 11 and 12, there is illustrated a guide wire 40 according to another embodiment of the invention. The guide wire 40 is substantially similar to the guide wire 1 and similar components are identified by the same reference numerals. The only difference between the guide wire 40 and the guide wire 1 is that the sleeve 12 comprises the spring 15, the ring 21 and a sleeve 41 of plastics material. The spring 19 has been omitted. In this embodiment of the invention the ring 21 which is brazed to the spring 15 and to the wire core 2 centrally locates the sleeve 41 relative to the wire core 2. Otherwise, the guide wire 40 is similar to the guide wire 1.

Referring now to Figs. 13 to 16, there is illustrated further alternative distal portions 45 to 47 of guide wires also according to the invention. The guide wires would be similar to the guide wire 1, and the distal portions 45 to 47 are substantially similar to the distal portion 4 of the guide wire 1, and similar components are identified by the same reference numerals. The main difference between the distal portions 45 to 47 and the distal portion 4 of the guide wire 1 is that the reinforcing ridges 25 are either offset from the axial centreline or extend at an angle to the axial centreline.

In the distal portion 46 the reinforcing ridge as well as being tapered towards the distal end to merge with the major surface 16 towards the distal end, opposite faces 50 and 51 of the reinforcing ridge 25 also taper towards the distal end.

The reinforcing ridge 25 of the distal portion 47 extends longitudinally and parallel with the minor surfaces 18 of the distal portion 47.

Referring now to Figs. 17(a) to (p), there is illustrated a plurality of alternative distal portions for guide wires according to the invention. For convenience the distal portions are identified by the reference numeral 60, and components which are similar to the distal portion 4 of the guide wire 1 are identified by the same reference numerals.

In the distal portions of Figs. 17(a) and (h) the means for retaining the distal portion with the desired curved configuration set in the distal portion is provided by forming the reinforcing ridge 25 by shaping the distal portion 60. In the distal portion of Fig. 17(j) the means for retaining the desired curved configuration set in the distal portion is also provided by shaping the distal portion, however, a ridge in this embodiment of the invention is not formed. Rather, a twist is induced in the distal portion 60.

In the distal portion 60 of Fig. 17(b) a pair of reinforcing ridges are provided on the respective opposite major surfaces 16 and 17. Similarly, in the distal portion 60 of Figs. 17(e), (k), (l), (n) and (o) the reinforcing ridges 25 are provided on the respective opposite major surfaces 16 and 17. The distal portion 60 of Fig. 17(i) is

similar to that of Fig. 17(e) with the exception that only a single reinforcing ridge 25 is provided.

In the distal portion 60 of Fig. 17(m) and (p) instead of the reinforcing means being formed by reinforcing ridges 25, the reinforcing means are provided by increasing the cross-section of the distal portion 60 adjacent the edges defining the minor surfaces 18.

Otherwise the reinforcing ridges 25 provided on the distal portion 60 of the remaining distal portion 60 of Fig. 17 are clear from the drawings.

While the guide wire has been described for use with a catheter, it is envisaged that in certain cases the guide wire may be used without a catheter.

The invention is not limited to the embodiment hereinbefore described, which may be varied in construction and detail.

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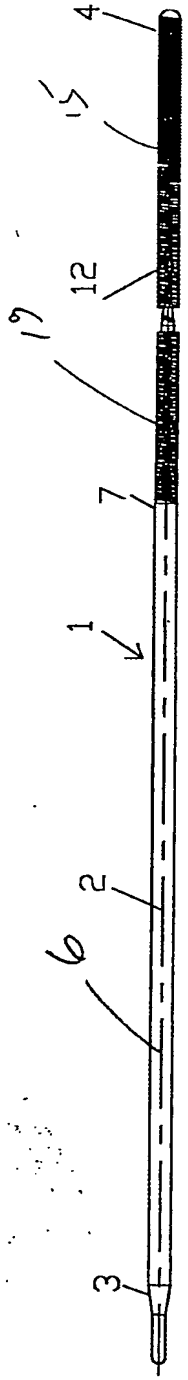


Fig 1

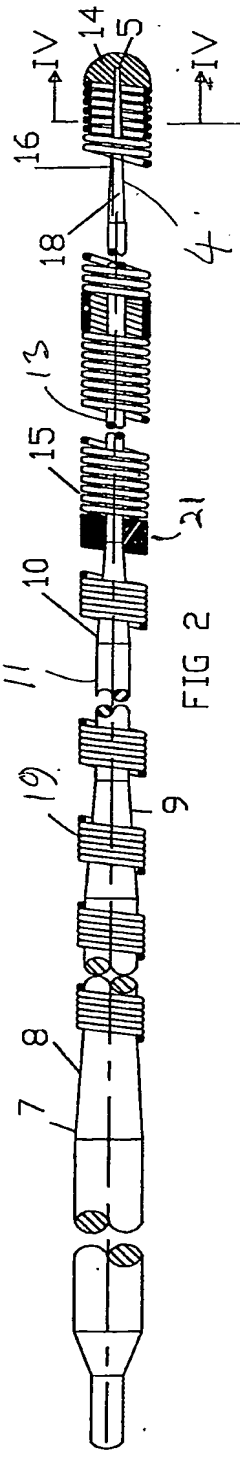


FIG 2

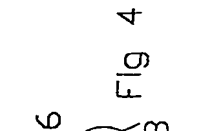


Fig 4

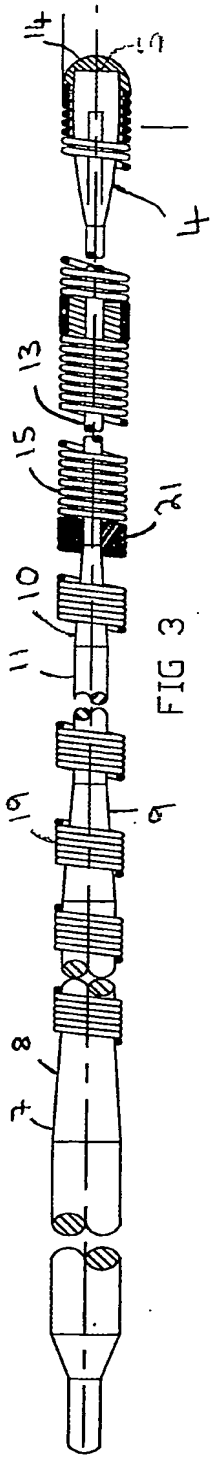


FIG 3

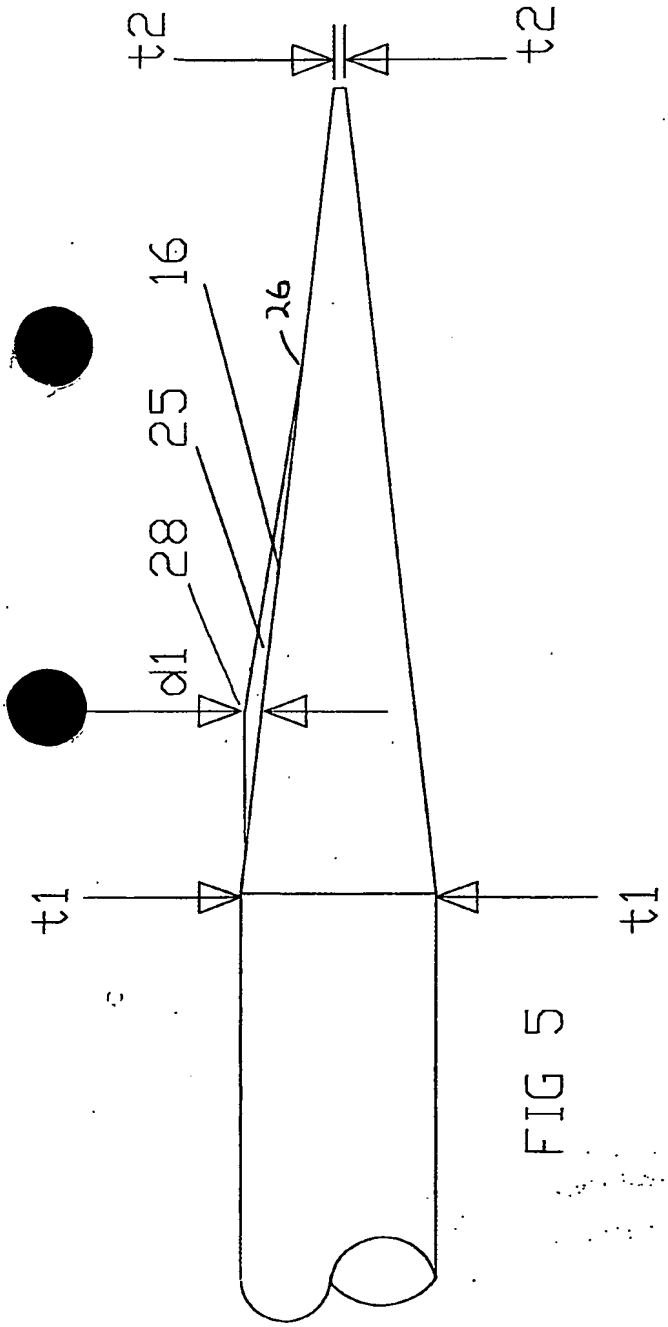


FIG 5

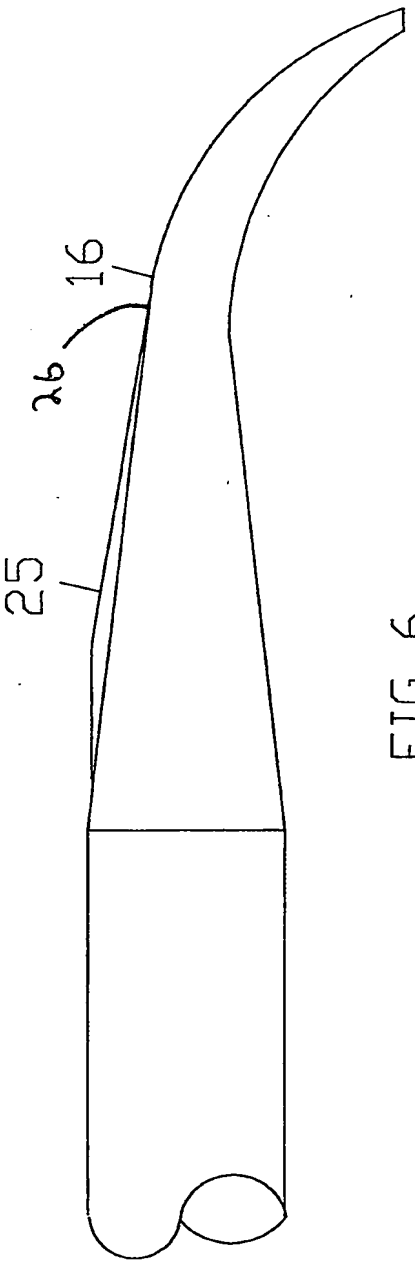


FIG 6

FIG 7(a)

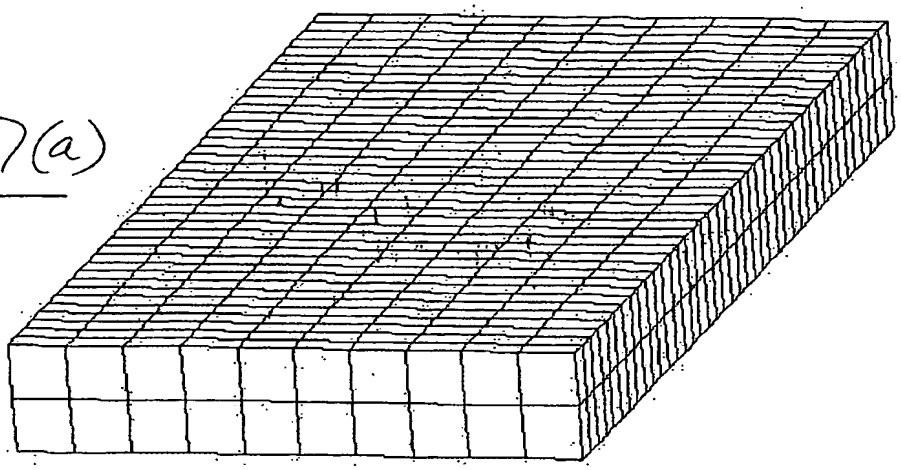
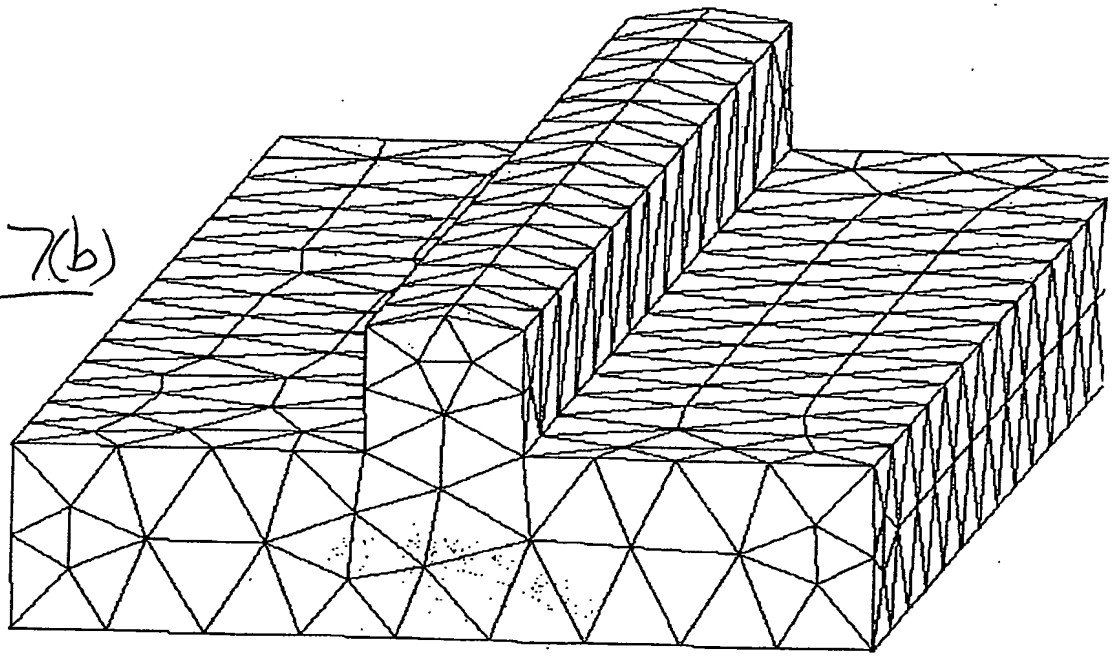


FIG 7(b)



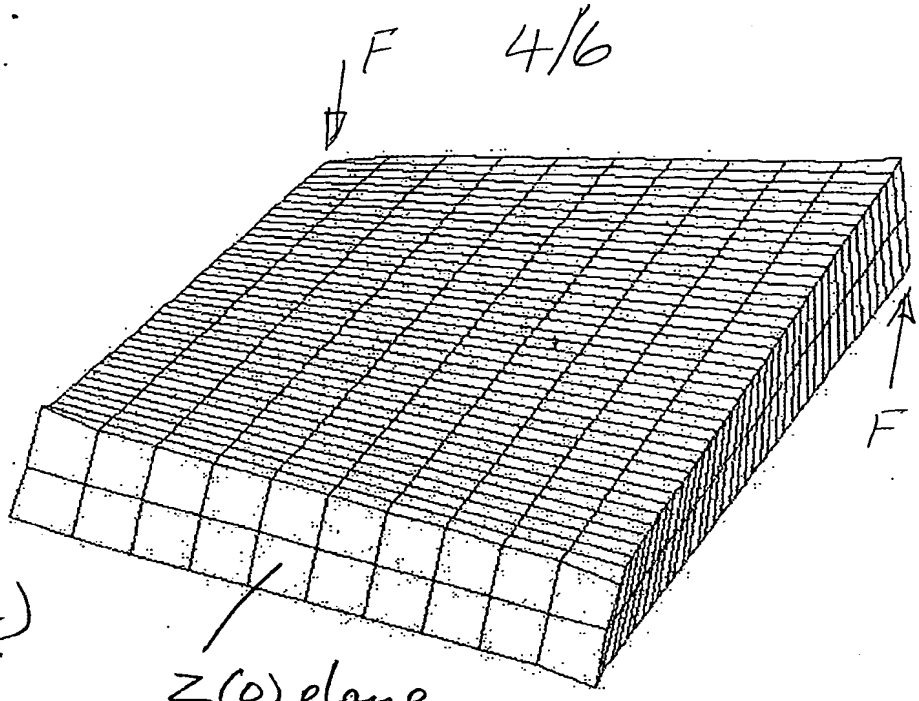


FIG 8(a)

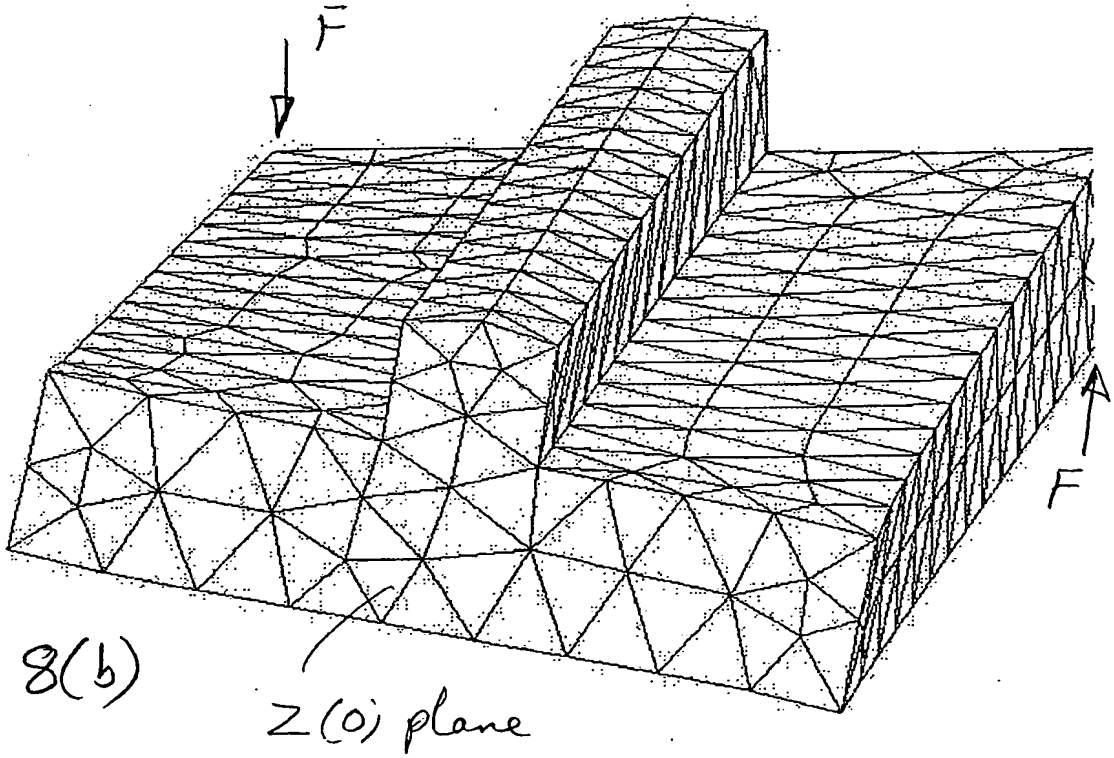


FIG 8(b)

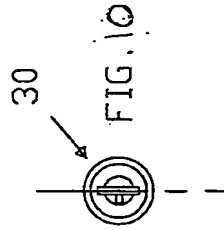


FIG. 10

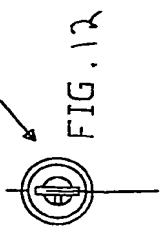


FIG. 12

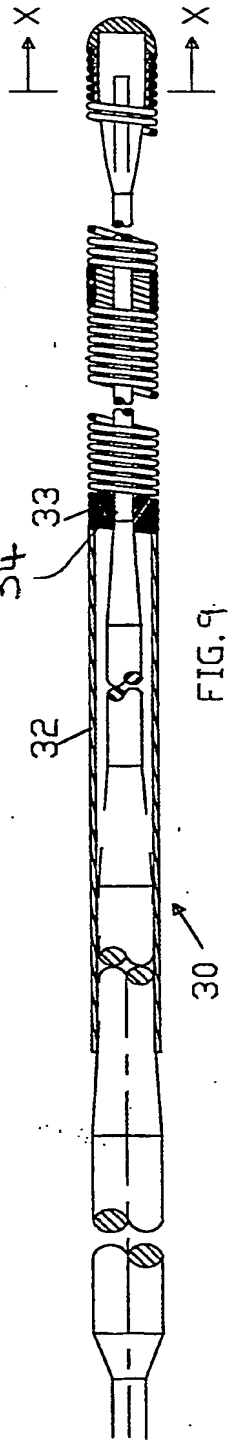


FIG. 9

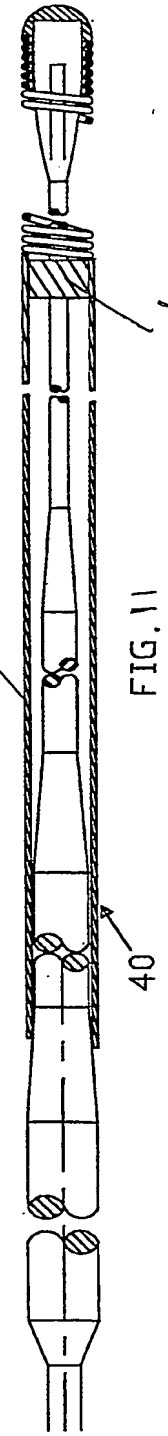


FIG. 11

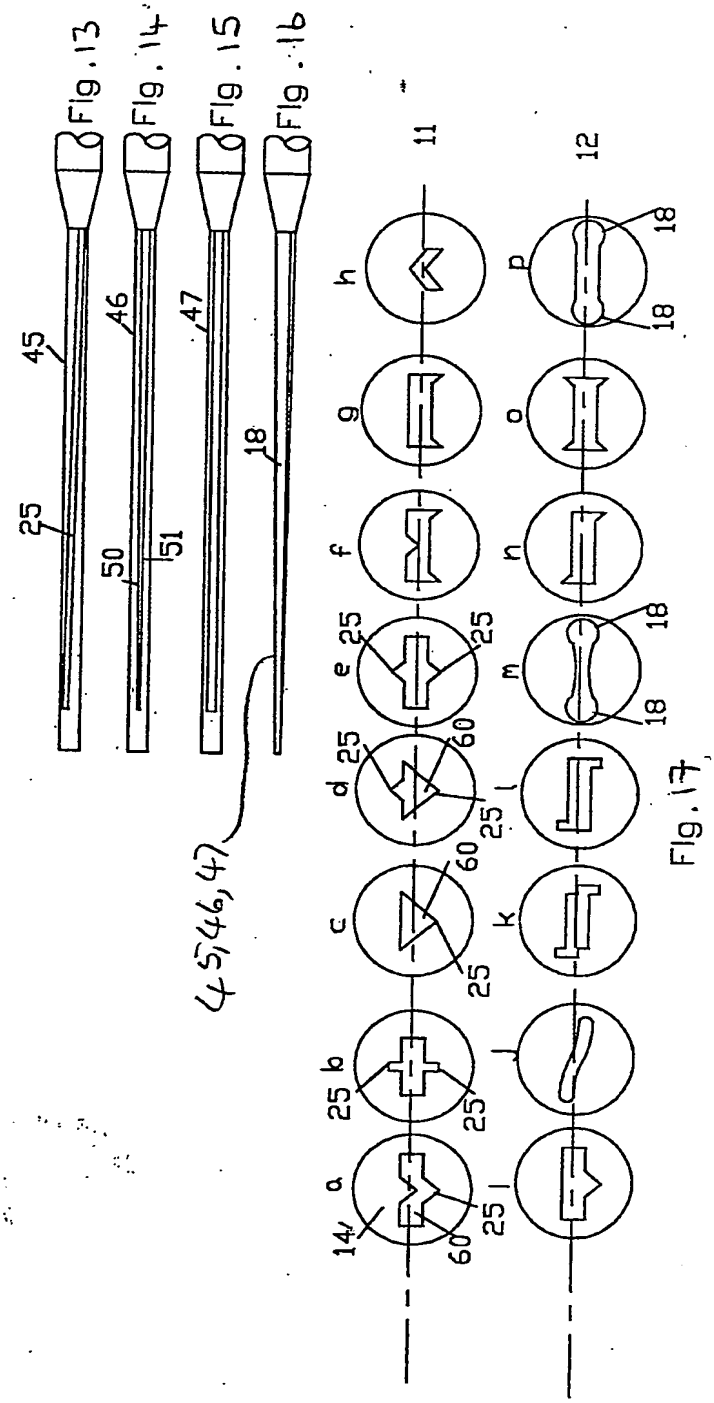


Fig. 13
Fig. 14
Fig. 15
Fig. 16
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Fig. 17